DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

93137d

Food and Drug Administration
555 Winderley Pl., Ste. 200
Maitland, Fl 32751

VIA FEDERAL EXPRESS

WARNING LETTER

FLA-02-32

February 22, 2002

William H. Valdes, President
Chef's Creations Inc.
408 Virginia Drive
Orlando, Florida 32803

Dear Mr. Valdes:

We inspected your firm at the above address on April 26, and May 1, 3, and 7, 2001, and found that you have serious deviations from the Seafood HACCP regulations (21 CFR Part 123). We apologize for not writing to you sooner regarding these deviations. The deviations cause your Clam Chowder, Conch Chowder, Lobster Bisque, Golden Lobster Bisque and Crab Bisque to be in violation of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act. You can find this Act and these regulations through links in FDA's home page at www.fda.gov.

The deviations are as follows:

1. You must have a HACCP plan that list the food safety hazards that are reasonably likely to occur, to comply with CFR 123.6 (c) (1). Your firm's HACCP plan for Fully Cooked, Not Shelf Stable Seafood Products, which includes: Clam Chowder, Conch Chowder, Lobster Bisque, Golden Lobster Bisque, and Crab Bisque, does not list the food safety hazards of pathogen survival through cooking, pathogen growth through time and temperature abuse, and *Clostridium botulinum* toxin formation at the appropriate critical control points in your HACCP plan.

2. You must have a HACCP plan that lists the critical control points, to comply with 21 CFR 123.6(c)(2). Your firm's HACCP plan for Clam Chowder does not list the critical control point of receiving ingredients for controlling the food safety hazard of pathogen growth through time and temperature abuse. Our investigator noted that your firm's HACCP plan does not identify the receiving of such ingredients as refrigerated clam base. In an updated hazard analysis received in our office from Bryan Neubauer on May 18, 2001, receiving of non-shelf stable seafood products appears to have been updated by your firm as a critical control point under "R1", however, it is unclear as to whether this is now in your HACCP plan for these products.

3. You must have a HACCP plan that lists the critical limits that must be met, to comply with 21 CFR 123.6(c)(3). Your firm's HACCP plan for Fully Cooked, Not Shelf Stable Seafood Products lists an inadequate critical limit at the Cooking (CCP1) critical control point to control pathogen survival through cooking. Your HACCP plan states that your products must obtain a minimum internal temperature of [redacted], but this temperature is not adequate to inactivate *Clostridium botulinum* spores which could germinate, since this product is stored refrigerated at 45°F.

4. You must have a HACCP plan that lists the critical limits that must be met, to comply with 21 CFR 123.6(c)(3). Your firm's HACCP plan for Fully Cooked, Not Shelf Stable Seafood Products lists a critical limit of "Finished product storage areas will not exceed [redacted] at the Finished Product Storage (S2) critical control point that is not adequate to control *Clostridium botulinum* toxin formation. The minimum temperature for growth and toxin formation by *Clostridium botulinum*, type E and nonproteolytic types B and F is 38°F.

5. You must have a HACCP plan that lists the monitoring procedures for each critical control point, to comply with 21 CFR 123.6(c)(4). Your firm's HACCP plan for Fully Cooked, Not Shelf Stable Seafood Products lists a monitoring procedure at the Finished Product Storage (S2) critical control point that is not adequate to control the pathogen growth and toxin formulation, and *Clostridium botulinum* toxin formation hazards. Your HACCP plan lists an inadequate monitoring frequency of checking the refrigeration temperature of your seafood product storage areas at least twice per day. Unless your products are stored under ice or other cooling media, monitoring must be continuous by an instrument itself, with a visual check of that instrument at least once per day. This instrument should involve a digital time/temperature data logger, recorder thermometer, or a high temperature alarm with 24-hour monitoring.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the Seafood HACCP regulations and the Good Manufacturing Practice regulations (21 CFR Part 110). You also have a responsibility to use procedures to prevent further violations of the U.S. Federal Food, Drug, and Cosmetic Act and all applicable regulations.

We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your aforementioned products and/or enjoin your firm from operating.

Please respond in writing within three (3) weeks from your receipt of this letter. Your response should outline the specifics you are doing to correct these deviations. You may wish to include in your response documentation such as amended HACCP plans, monitoring records, revised forms, or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deviations.

Please send your reply to the Food and Drug Administration, Attention: Diane Englund, Compliance Officer, 555 Winderly Place, Suite 200, Maitland, Florida, 32751. If you have any questions regarding any issue in this letter, please contact Ms. Englund at (407) 475-4741.

Sincerely,

Kendall W. Hester

for Emma Singleton
District Director
Florida District Office